

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

DR. JOSEPH CICCIO et al.,

Plaintiffs,

v.

SMILEDIRECTCLUB, LLC et al.,

Defendants.

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**Case No. 3:19-cv-00845
Judge Aleta A. Trauger**

MEMORANDUM & ORDER

On June 22, 2022, the defendants filed a Motion for Review of Nondispositive Orders of Magistrate Judge (Doc. No. 358), to which the plaintiffs have filed a Response (Doc. No. 365). On June 30, 2022, the defendants filed a second Motion for Review of Nondispositive Magistrate Judge Order (Doc. No. 360), to which the plaintiffs have filed a Response (Doc. No. 368). For the reasons set out herein, both motions will be denied.

I. BACKGROUND

Defendant SmileDirectClub, LLC (“SmileDirect”) sells plastic dental aligners as an alternative to conventional orthodontics. The plaintiffs are orthodontists and orthodontic practices who allege that they have been harmed by SmileDirect’s use of deceptive marketing to entice potential customers away from more traditional treatments. The parties are in discovery, for which a Special Master has been appointed. That discovery has been bifurcated into a stage focused on class certification and a later stage focused on the merits, and the case is currently in the first of those two stages.

The defendants seek review of the Magistrate Judge’s determinations regarding two sets of discovery requests: (1) the Magistrate Judge’s decision not to require the plaintiffs to produce certain information regarding the geographic markets of their clinics; and (2) the Magistrate Judge’s decision to compel the production of certain documents that the defendants assert to be privileged. Each of those decisions was considered in the first instance by the Special Master, then unsuccessfully challenged by the defendants before the Magistrate Judge. The defendants now argue that both the Special Master and Magistrate Judge erred.

A. The Geographic Market Requests

The defendants “respectfully request that the Court compel responses to Interrogatory No. 6 (seeking zip codes of Entity Plaintiffs’ patients), Interrogatory No. 12 (asking Provider Plaintiffs to identify the geographic boundaries of the consumer market for their traditional orthodontic services)[,] and to Request for Production No. 34 (seeking documents that identify or describe that same consumer market).” (Doc. No. 358 at 1–2.) In rejecting those requests, the Special Master wrote:

At this stage of the litigation—which is focused on class discovery—it is unclear how any of the requested information is relevant to the issue of class certification. Whether Provider Plaintiffs draw patients from 1 mile or 2 miles or some other radius does not seem to bear on the issue of whether or not a class should be certified and whether or not any of the Provider Plaintiffs would be an appropriate class representative. The Defendants have, on more than one occasion, requested ZIP code data for the Provider Plaintiffs. But nothing in the parties’ briefing or the Defendants’ explanation for why they required that data at the certification stage at the December 8, 2021, hearing was compelling. Accordingly, Defendants’ requested relief concerning Interrogatory Nos. 6 and 12 and RFP No. 34 is DENIED.

(Doc. No. 317 at 9.) The defendants appealed the Special Master’s conclusion to the Magistrate Judge, who overruled their objections. Regarding the request for general information about

geographic consumer markets embodied in Interrogatory No. 12 and Request for Production No. 34, the Magistrate Judge wrote:

The Court finds no abuse of discretion in the Special Master's ruling. First, the Special Master highlighted the failure of Defendants to provide any compelling argument, either in their briefing or during a December 2021 hearing on the issue, that the discovery currently sought has any bearing on class certification. (Docket No. 317 at 9.) Additionally, while Defendants contend that the information they seek is relevant to class certification because it would demonstrate whether the purported class has in fact suffered the harm alleged by Provider Plaintiffs (Docket No. 322 at 5-7), Provider Plaintiffs note that Defendants already know the locations of Provider Plaintiffs' practices—and thus the approximate scope of their consumer markets—and can therefore make any geographic argument against class certification based on such information. (Docket No. 328 at 4.)

Moreover, Provider Plaintiffs' responses to Interrogatory No. 12 and Request for Production No. 34 indicate that they are not currently in possession of any "surveys, studies, reports, or data" identifying the geographic boundaries of any relevant consumer market. (Docket No. 328 at 1-2.) And as discussed by the Special Master, Provider Plaintiffs remain obligated to supplement these discovery responses if any relevant documents are produced or discovered during the ongoing course of litigation. (Docket No. 317 at 7-8.) For all of these reasons, the Court finds no basis on which to conclude that the Special Master abused his discretion.

Accordingly, Defendants' Objection (Docket No. 322) is **OVERRULED**.

(Doc. No. 352 at 2–3.)

Regarding the request for patient zip codes in Interrogatory No. 6, the Magistrate Judge wrote:

Defendants object . . . to the portion of the Special Master's order prohibiting them from propounding one particular interrogatory—identified as Interrogatory No. 6—which asks the Provider Plaintiffs to identify the zip codes of each of their patients. (Docket No. 327 at 1.) However, in lieu of new arguments as to why the Special Master's decision should be reversed, Defendants "refer to and incorporate as if fully stated here" the objection and accompanying brief they previously filed in response to a separate Special Master order, found at Docket No. 317, which prevented Defendants from obtaining information relating to Provider Plaintiffs' "geographic markets." (Docket No. 327 at 1; Docket No. 322 at 1.) The similarity in these discovery requests ostensibly forms the basis of Defendants' decision to forego additional briefing in connection with the instant objection.

The Court certainly appreciates Defendants' efforts to avoid rehashing prior arguments. By the same token, however, the Court sees no reason to depart from its prior ruling on Defendants' objection to the Special Master order regarding Provider Plaintiffs' geographic markets, found at Docket No. 352. For the same reasons articulated in that order entered on June 8, 2022, the Court will overrule Defendants' objections to the Special Master order here.

(Doc. No. 353 at 2.)

In keeping with their approach to the zip code issue before the Magistrate Judge, the defendants have not filed any fresh briefing explaining why the Magistrate Judge's determinations were supposedly erroneous. Rather, the defendants merely argue that, "[f]or the reasons stated in Defendants' prior briefing (*see* ECF No. 317; ECF No. 322; ECF No. 327), which is adopted and incorporated herein by reference, allowing Plaintiffs [to] avoid substantively responding to these three requests is clearly erroneous and contrary to law." (Doc. No. 358 at 1.) As the Magistrate Judge noted, however, the most recent of those three incorporated-by-reference filings merely "refer[s] to and incorporate[s]" the earlier two for the purpose of extending their arguments to Interrogatory No. 6. (Doc. No. 327 at 1.)

B. The Privilege Claims

In the defendants' second Motion for Review—which, unlike the prior one, is supported by its own briefing—the defendants "respectfully request that the Court overturn the Magistrate Judge's Order requiring production of" documents reflecting "certain communications with the U.S. Food & Drug Administration Third Party Review Group, Ian Kitching, MRC-X, and Knoell USA." (Doc. No. 360 at 1.) The defendants concede that none of those people or entities were attorneys representing SmileDirect. The defendants argue, however, that the nature of those parties' relationships to SmileDirect—and in particular SmileDirect's legal department—entitle the underlying communications to protection.

1. FDA Third Party Review Group. “Under third-party review, an accredited third party evaluates the 510(k),¹ documents the review[,] and makes a recommendation to the FDA concerning the substantial equivalence of the device or initial classification.” Guide to Med. Device Reg. ¶ 804, 2019 WL 1552330 (Dennis Tosh ed., 2022); *see* 21 U.S.C. § 360m. The FDA Third Party Review Group is one such accredited group. According to the defendants, SmileDirect’s “legal department hired the FDA Third Party Review Group” to “provide advice regarding [SmileDirect’s] 510(k) submission.” (Doc. No. 325 at 5.)

2. Ian Kitching. According to the defendants, “Ian Kitching was a consultant for SmileDirect and SmileDirect’s General Counsel” who was “retained . . . to assist in providing legal advice regarding the 510(k) process.” (Doc. No. 295 at 18; Doc. No. 325 at 5.) Kitching “provided advice and perspective to SmileDirect’s counsel regarding the 510(k) process.” (Doc. No. 325 at 5.)

3. MRC-X & Knoell USA. The defendants state that “SmileDirect retained MRC-X and Knoell USA [as consultants] to provide information related to strategic legal decisions regarding the 510(k) process.” (Doc. No. 325 at 6.) The defendants complain that the record involving these two consultants is incomplete. Specifically, the defendants point out that they “did not provide any documents regarding [SmileDirect’s] relationship with MRC-X or Knoell USA to the Special Master,” based on the their understanding, at the time, that the nature of the relationship between SmileDirect and those parties was not in dispute. (*Id.*)

¹ As the court has discussed in detail previously in this case, the 510(k) clearance process is a widely-used mechanism for obtaining FDA permission to sell a medical device without undergoing full premarket approval.

II. LEGAL STANDARD

The standard of review applicable to a party's objections to a magistrate judge's ruling depends upon whether the objections pertain to a dispositive or non-dispositive matter. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(a). The dispute at issue in the Magistrate Judge's Order involves the scope of discovery and, as such, is non-dispositive. *See Burghardt v. Ryan*, No. 5:19-CV-325, 2020 WL 4350049, at *2 (N.D. Ohio July 29, 2020). The court's review of a magistrate judge's resolution of a non-dispositive pretrial matter is limited to determining whether the order is "clearly erroneous" or "contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); *see also Massey v. City of Ferndale*, 7 F.3d 506, 509 (6th Cir. 1993) ("When a magistrate judge determines a non-excepted, pending pretrial matter, the district court has the authority to 'reconsider' the determination, but under a limited standard of review.").

Under this standard, the court is not empowered to reverse the magistrate judge's ruling simply because this court would have decided the issue differently. "A finding [of fact] is 'clearly erroneous' when[,] although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Adams County Reg'l Water Dist. v. Vill. of Manchester*, 226 F.3d 513, 517 (6th Cir. 2000) (quoting *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)). A legal conclusion is "contrary to law" if it contradicts or ignores applicable precepts of law, as found in the Constitution, statutes, or case precedent. *Gandee v. Glaser*, 785 F. Supp. 684, 686 (S.D. Ohio 1992).

III. ANALYSIS

A. The Request for Geographic Information

The defendants have not identified any meaningful basis for reversing the Magistrate Judge's rulings regarding geographic discovery. The court does not doubt that issues of geography

bear on the plaintiffs' claims and even on some aspects of class certification. For example, a clinic dozens of miles from any SmileDirect customer would presumably have a harder time establishing that it lost business to SmileDirect than a clinic surrounded by such customers would. That distinction, in turn, would bear on the extent to which those two clinics' claims could be resolved in tandem through the class action process. The fact that geographic markets matter to the plaintiffs' theory generally, however, does not mean that the particular information requested was discoverable.

Interrogatory No. 12 and Request for Production No. 34 appear to have been formulated based on the unsupported assumption that the plaintiff clinics functioned with well-defined—and internally documented—geographic markets, which does not appear to be the case. Interrogatory No. 6's request for patient zip codes is at least more tethered to actual information likely to be in the plaintiffs' possession, but, as the Magistrate Judge noted, it is unclear why that information is necessary, particularly at the class certification stage, given that the defendants already have the clinics' addresses and therefore can make any geography-based arguments already. The court accordingly will not reverse the Magistrate Judge's decision to deny the requested geographic discovery.

B. The Defendants' Assertions of Privilege

The defendants argue first that the court should reverse the Magistrate Judge's ruling regarding the allegedly privileged documents on the ground that the Magistrate Judge failed to recognize that the Special Master had not "appl[ied] the correct legal standard to privileged communications involving third parties." (Doc. No. 361 at 4 (citing Doc. No. 319 at 6).) Specifically, the defendants argue that the Special Master incorrectly assumed that "a communication with a third party cannot be privileged unless the third party itself was providing

legal advice.” (Doc. No. 361 at 4 (citing Doc. No. 319 at 6).) If the Magistrate Judge *had* applied such a standard, it would indeed have been error. The court is aware of no authority that would support that formulation of the underlying rule, and the plaintiffs do not argue that such a rule, if applied, would have been correct. Far less apparent, however, is the fact that the Special Master actually made any such mistake. The defendants, rather, appear to be basing their argument on a misreading of one sentence from the Special Master’s Report that, while arguably ambiguous, does not, by either the court’s or the Magistrate Judge’s reading in context, endorse such a misunderstanding.

In the relevant passage, the Special Master, quoting an opinion of Chief Judge Haynes, wrote that attorney-client privilege would only apply if the third parties at issue were “retained by counsel for the purpose of providing legal advice.” (*Id.* at 6–7 (*quoting Genesco, Inc. v. Visa U.S.A., Inc.*, 302 F.R.D. 168, 190 (M.D. Tenn. Mar. 10, 2014))). The defendants read that sentence to mean that the Special Master believed that privilege only extends to a non-attorney third party if that third party was retained by counsel for the purpose of *the non-attorney third party’s* providing legal advice. The privilege extended by such a test would be scant indeed, given that the ability of a non-attorney to lawfully provide “legal advice” in Tennessee is limited. *See* Tenn. Code Ann. § 23-3-103 (prohibiting unauthorized practice of law); *see also* Tenn. Code Ann. § 23-3-101(3) (defining “[p]ractice of law”). There is, however, another plausible reading of the quoted language that is more consistent with the ordinary role played by non-lawyers in legal settings. Because the quoted sentence does not explicitly state who would be “providing [the] legal advice” for which the consultant was retained, the sentence can also be construed, in the alternative, to say that attorney-client privilege may extend to communications involving a third party who was

retained to provide support for the *attorney's own* provision of legal advice.² The Magistrate Judge, moreover, acknowledged that ambiguity and therefore considered the Special Master's analysis as a whole, concluding that, "[i]n context, the Special Master's ruling clearly was not based on the" assumption that a third party must itself be engaged in the direct provision of legal advice for the underlying communications to be privileged. (Doc. No. 355 at 6.) One errantly ambiguous sentence, included in an otherwise appropriate treatment of the issues raised, would not provide a basis for reversing the Special Master's resolution of a nondispositive issue. Rather, if the court is to reject the conclusion reached by the Special Master and affirmed by the Magistrate Judge, it must do so based on some error in their underlying analysis. The court will therefore turn to the Magistrate Judge's consideration of the Special Master's substantive reasoning.

As the Special Master and the Magistrate Judge correctly observed, "[b]oth the attorney-client privilege and work-product protection are," generally speaking, "waived by voluntary disclosure of private communications to third parties." *New Phoenix Sunrise Corp. v. Comm'r*, 408 F. App'x 908, 918 (6th Cir. 2010) (citing *United States v. Dakota*, 197 F.3d 821, 825 (6th Cir. 1999); *In re Columbia/HCA Healthcare Corp.*, 293 F.3d 289, 306 (6th Cir. 2002)). Protection may extend, however, to communications made by or to a third party "to assist the attorney in giving legal advice to the client." *In re OM Sec. Litig.*, 226 F.R.D. 579, 588 (N.D. Ohio 2005) (citing *United States v. Kovel*, 296 F.2d 918, 922 (2d Cir. 1961); *Toler v. United States*, No. 2:01-MS-004, 2003 WL 21255039, at *4 (S.D. Ohio Apr. 29, 2003)). It does not appear to be disputed that

² The permissibility of such a reading can be demonstrated by considering the same syntax in a less ambiguous setting. A person might say, for example, that he or she had "hired a caterer for the purpose of throwing a party," and a reasonable, ordinary listener would, of course, understand that it would not be the *caterer* throwing the party, but rather the speaker who hired the caterer—even though the sentence itself did not explicitly resolve that ambiguity. Similarly, an attorney might hire a consultant for the purpose of the attorney's providing legal advice to the attorney's client with that consultant's support or assistance, and that relationship could be described as the consultant's having been hired "for the purpose of providing legal advice."

SmileDirect's consultants did, in fact, take part in a broad process through which multiple entities and individuals, including some lawyers, provided advice to SmileDirect about its dealings with the FDA. If, therefore, privilege could be obtained simply by a consultant's provision of or assistance with advice *adjacent to* a lawyer's advice on a legal issue, then privilege would probably apply here. Adjacency, though, is not the standard; the third party must have a connection to the legal advice itself.

Determining whether the advice offered or supported by a consultant is actually "legal" in nature, though, can be a challenge—particularly in a heavily regulated industry such as healthcare. Nearly every major healthcare business decision has at least the potential for some regulatory/administrative implications, but courts have generally recognized "the principle that compliance with regulations is usually a business matter, not a legal one." *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 9211219, at *1 (N.D. Ohio Mar. 30, 2020) (citing *FTC v. Abbvie, Inc.*, No. CV 14-5151, 2015 WL 8623076, at *3 (E.D. Pa. Dec. 14, 2015); *Zigler v. Allstate Ins. Co.*, No. 1:06-CV-2112, 2007 WL 1087607, at *1 (N.D. Ohio Apr. 9, 2007)). Accordingly, in order "to be privileged, [a] communication must have the primary purpose of soliciting [or conveying] legal, rather than business advice." *Abington Emerson Cap., LLC v. Landash Corp.*, No. 2:17-CV-143, 2019 WL 13161925, at *2 (S.D. Ohio Oct. 9, 2019) (quoting *Zigler*, 2007 WL 1087607, at *1).

The Magistrate Judge considered this issue in light of the established, if sometimes fuzzy, boundary between legal advice and business advice related to regulatory matters and found no abuse of discretion by the Special Master. (*See* Doc. No. 319 at 11–13.) That conclusion is unsurprising; the ambiguity involved in the regulatory/legal distinction means that, as a practical matter, showing a clear error or abuse of discretion under the standard is difficult. Indeed, the

defendants, presumably recognizing that fact, state that they “do not challenge the Special Master’s ruling based on his distinction between legal advice and regulatory advice.” (Doc. No. 361 at 3.) But if the defendants do not challenge that portion of the Special Master’s analysis—and, as the court has held, the defendants’ arguments regarding the Special Master’s supposedly mistaken standard are unpersuasive—then it is difficult to see what basis the court could have for rejecting the Special Master’s conclusions.

The Special Master reviewed individual, representative communications *in camera* and determined that they fell on the business, not legal, side of the applicable line. The court has also confirmed with the Magistrate Judge that she obtained access to the documents under *in camera* review, which the court has now done as well. The court, like the Magistrate Judge, sees no clear error in the Special Master’s interpretation. For example, the Special Master found that the emails between SmileDirect and Kitching consisted of “nothing more than updates on the 510(k) application process, the application itself, and deficiencies identified by the FDA Third Party Review Group.” (Doc. No. 319 at 9.) Based on that review, the Special Master found the consultants’ work to involve regulatory, not legal, advice. The Magistrate Judge found no abuse of discretion in that conclusion, and the court agrees.

Finally, the defendants argue that the Magistrate Judge erred in her consideration of the documents related to MRC-X and Knoell USA by failing to give the defendants sufficient opportunity to supplement the record with background materials establishing privilege related to those entities. The defendants describe the situation as follows:

Defendants had no notice that the privileged status of MRC-X and Knoell USA would be at issue before the Special Master. These parties only happened to be included on communications the Special Master reviewed for other issues. Had Defendants known these parties’ privilege status would be at issue, they could have and would have provided evidence regarding their status.

(Doc. No. 361 at 2–3.) The references to “privileged status”—or “privilege status,” given that the defendants use both—confuses the issue somewhat. Privilege applies to documents and communications, not people or entities; even an attorney himself does not enjoy a special status rendering all his communications protected, regardless of their purpose or content. *See Bd. of Commissioners of Clermont Cnty., Ohio v. EPA*, No. 1:17-CV-389, 2021 WL 391715, at *6 (S.D. Ohio Feb. 4, 2021). Issues of characterization aside, however, the court takes the defendants to argue that they should have been permitted to present more evidence to support the conclusion that MRC-X and Knoell USA were retained to support the provision of legal advice, which the defendants would then use in support of their claims for document-specific privilege.

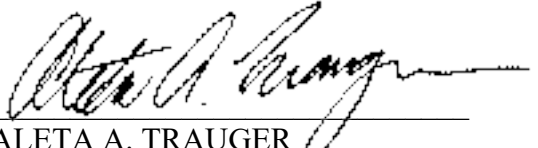
The Magistrate Judge considered this argument and concluded, among other things, that the defendants had not shown that additional evidence would have affected the Special Master’s conclusions. (Doc. No. 355 at 9–10.) The defendants, by now, have had ample opportunity to establish otherwise, and they have not. The court, moreover, shares the Magistrate Judge’s assessment that additional evidence about the general relationship between SmileDirect and its consultants would be unlikely to negate the conclusion reached by the *in camera* review of representative communications themselves. The legal and business considerations at issue in the FDA clearance process are so closely intertwined that whether particular advice was directed at one or the other is almost certainly better evaluated in light of the content of representative documents, rather than parties’ potentially self-serving characterizations of the underlying relationships. If a party had the power to confer “privileged status” on any regulatory consultant simply by describing the consultant in the right way internally, it would vitiate the distinction between regulatory and legal advice altogether.

“The burden of establishing privilege rests with the person asserting it.” *Avis Rent A Car Sys., LLC v. City of Dayton, Ohio*, No. 3:12-CV-399, 2013 WL 3781784, at *8 (S.D. Ohio July 18, 2013) (quoting *In re Grand Jury Investigation No. 83-2-35*, 723 F.2d 447, 450 (6th Cir. 1983)). Even if the defendants were initially confused about which aspects of that burden were to be considered by the Special Master, they have had plenty of time to argue their case now. *See Banner v. City of Flint*, 99 F. App'x 29, 35 (6th Cir. 2004) (noting that the law does not forbid “the district court to take new evidence in non-dispositive matters referred to a magistrate judge”). Because the defendants have failed to identify any clear error by the Magistrate Judge in her review of the Special Master’s conclusions, the court will deny the defendants’ motion.

IV. CONCLUSION

For the foregoing reasons, the defendants’ Motion for Review of Nondispositive Orders of Magistrate Judge (Doc. No. 358) and Motion for Review of Nondispositive Magistrate Judge Order (Doc. No. 360) are hereby **DENIED**.

It is so **ORDERED**.



ALETA A. TRAUGER
United States District Judge